PSJ15 Exh 28





To learn more about how you can help, call us at 1-800-233-8969 or visit our Web site:

www.caresalliance.org

C.A.R.E.S. Alliance Tools Catalog and Order Form

Tools for Improving Chronic Pain Patient Care and Quality of Life Through Education

Sponsored by



C.A.R.E.S. Alliance was created to help patients, healthcare professionals, nonprofit organizations, and people in the pharmaceutical industry work together to improve patient safety.

Provided as an educational resource by C.A.R.E.S. Alliance

COVIDIEN, COVIDIEN with logo and Covidien logo are U.S and internationally registered trademarks of Covidien AG. C.A.R.E.S. Alliance is a service mark of Mallinckrodt Inc. © 2011 Covidien. CA-XXX November 2011. Printed in USA.

COVIDIEN
675 McDonnell Blvd
Hazelwood, MO 63042
www.covidien.com

Introduction

Incoming Ibos

C.A.R.E.S. Alliance encourages and facilitates collaboration among all stakeholders to gain new insight into the safe use of opioids for managing pain and to develop innovative new educational resources that will advance best practices in the treatment of chronic pain. It is a voluntary initiative that provides educational programs and resources to support responsible prescribing and safe use of opioid analgesics. It is intended to be a one-stop resource for everyone who has a stake in opioid safety:

Professional societies

- Prescribers
- Pharmaceutical companies

Patients

- Patient safety organizations
- Pharmacists

C.A.R.E.S. Alliance is committed to providing education and resources to healthcare professionals (HCPs) and patients about medication risks, responsible prescribing, and safe use. Safe and effective therapy for the management of chronic noncancer pain requires clinical skills and knowledge of the principles of good opioid prescribing and the assessment and management of risks associated with opioids.¹

To support efforts to ensure the safe prescribing and use of opioid pain medications, C.A.R.E.S. Alliance has developed and assembled an array of tools to be used by prescribers, patients, and pharmacists. Some tools can help HCPs predict a patient's risk of abuse or addiction prior to treatment, whereas others can help identify aberrant behaviors once a patient has already started treatment with an opioid pain medication. In addition, HCPs can find clinical guidelines and best practices developed by leaders in the field of pain management as well as resources for patients to help them understand their medication, use their medication properly, and better communicate with their HCP. A number of tools are also available to help pharmacists responsibly dispense opioid pain medication to properly selected and counseled patients.

This catalog offers a list of the tools available from C.A.R.E.S. Alliance. Along with brief descriptions of each tool, the catalog contains a perforated order form with a checklist of all the tools included in this catalog. Check the boxes for the tools you wish to receive, and place the postage-paid, preaddressed order form in the mail. For a complete list of available tools, including videos available for download, visit the C.A.R.E.S. Alliance Web site at www.caresalliance.org.

General Opioid Management Tools

Opioid Clinical Management Guide

Item #CA-012

Availability: print, online



The Opioid Clinical Management Guide is a resource for responsible opioid prescribing and use that can help HCPs improve patient outcomes by enhancing knowledge of the potential risks, responsible prescribing, and safe use of opioid pain medications. The guide provides important information on misuse, abuse, addiction, overdose, adverse events, patient selection, monitoring, counseling, treatment initiation, and discontinuation.

Opioid Clinical Management Checklist

Item #CA-013

Availability: print, online



The Opioid Clinical Management Checklist is a companion to the Opioid Clinical Management Guide. It is a handy reminder for HCPs that touches on documentation, patient selection, risk stratification, counseling, and the 4 A's (Analgesia, Activities of daily living, Adverse effects, and Aberrant drug-related behaviors) of opioid pain medications.

^{1.} Chou R, Fanciullo GJ, Fine PG, et al. Clinical guidelines for the use of chronic opioid therapy in chronic noncancer pair J Pain. 2009;10(2):113-130.

Case: 1:17-md-02804-DAP Doc #: 2295-4 Filed: 08/14/19 4 of 14. PageID #: 362459

Opioid Treatment Guidelines Reprint Carrier

Item #CA-003RC

Availability: print



The Opioid Treatment Guidelines Reprint Carrier provides recommendations on the use of opioid pain medication to treat chronic noncancer pain. The guidelines were developed by a multidisciplinary expert panel after systematic review of the evidence and include suggestions on careful patient evaluation and structuring of opioid therapy to accommodate identified risk, appropriate initiation and titration, and regular and comprehensive patient monitoring.

Universal Precautions in Pain Medicine Reprint Carrier

Item #CA-006B

Availability: print



The Universal Precautions in Pain Medicine Reprint Carrier contains articles that describe a Universal Precautions approach to the assessment and ongoing management of patients with chronic pain, including the inherited pain patient. The articles propose a minimum level of care applicable to all patients presenting with chronic pain.

Urine Drug Screening (UDS) Reprint Carrier

Item #CA-005RC

Availability: print



The UDS Reprint Carrier provides the HCP with information on the limitations of UDS and assessment of results using both objective and clinical information. The document contains information on screenings for commonly abused drugs, including opioids, alcohol, amphetamines, benzodiazepines, marijuana, and cocaine.

Urine Drug Testing (UDT) Brochure

Item #CA-016

Availability: print, online



The UDT Brochure reinforces HCP knowledge of when, why, and how to use UDT, including advice about which screen to order. It provides information on the limitations of UDT, how to appropriately interpret results for commonly used drugs, and how to manage the patient-prescriber relationship when ordering UDT.

Case: 1:17-md-02804-DAP Doc #: 2295-4 Filed: 08/14/19 5 of 14. PageID #: 362460

Patient-Prescriber Expectations and Responsibilities Form

Item #CA-010

Availability: print, online

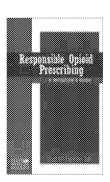


The Patient-Prescriber Expectations and Responsibilities Form can be used to help set expectations for both the patient and the HCP at the start of treatment with opioid pain medication. The HCP can use the points in the form as counseling opportunities. This form can also serve as documentation of patient understanding of the risks associated with treatment, the responsible manner by which the medicine will be received from a pharmacy, and the safe use and handling of opioid pain medications.

Responsible Opioid Prescribing: A Physician's Guide

Item #CA-002

Availability: print

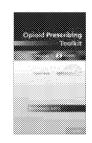


Authored by Scott M. Fishman, MD, Responsible Opioid Prescribing: A Physician's Guide provides effective strategies that HCPs can use to aid in the use of prescription opioids for chronic pain and to help reduce the risk of addiction, abuse, and diversion when prescribing opioid pain medication. It provides concise and pragmatic steps based on the Federation of State Medical Boards' Model Policy for the Use of Controlled Substances for the Treatment of Pain.

Opioid Prescribing Toolkit

Item #CA-004

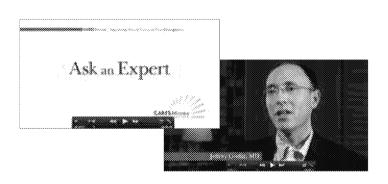
Availability: print



The Opioid Prescribing Toolkit is a workbook with accompanying CD-ROM that provides a comprehensive array of user-friendly tools to help HCPs safely and effectively prescribe opioid pain medication to patients with chronic pain.

Ask-an-Expert Video Series

Availability: online



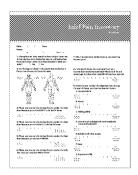
This video series features experts in the responsible prescribing of opioid analgesics for patients with chronic pain. Jeffrey Gudin, MD, discusses the importance of prescribing opioids responsibly, including appropriate patient selection, dosing, and counseling to ensure safe use. In addition, Steven D. Passik, PhD, and Lynn Webster, MD, focus their discussion on the importance of thorough assessment of risk for aberrant drug-related behaviors in every patient being considered for opioid therapy. The physicians discuss the elements of risk stratification, including use of validated risk stratification tools, prescription monitoring programs, and consultation with referring physicians and pharmacies to ensure appropriate use.

Validated Tools

Brief Pain Inventory (BPI)

Item #CA-007A

Availability: print, online



The BPI has been shown to be an effective tool for assessing pain in a wide range of clinical conditions. Patients answer questions that document the severity of their pain as well as the degree to which pain interferes with common dimensions of feeling and function.

Numeric Rating Scale (NRS) and Wong-Baker Faces Pain Rating Scale

Item #CA-007B

Availability: print, online



The NRS and the Wong-Baker Faces Pain Rating Scale are simple, easily administered reporting instruments that help to quantify a patient's pain before and throughout treatment. The NRS is administered by asking the patient to estimate his or her pain on a scale of 0 to 10. The Wong-Baker Faces Pain Rating Scale uses illustrated facial expressions to evaluate pain levels.

Opioid Risk Tool (ORT)

Item #CA-007C

Availability: print, online



The ORT is a simple 5-question assessment designed to predict which patients may develop aberrant drug-related behaviors based on known risk factors associated with abuse or addiction. The ORT is typically administered during the initial clinic visit. The ORT can either be self-administered by the patient or completed by the HCP as part of the patient interview.

Pain Assessment and Documentation Tool (PADTTM)

Item #CA-007D

Availability: print, online



The PADT is a clinician-directed interview tool designed to help assess a patient's pain level and how well that pain is being managed by treatment. The tool also allows for the documentation of adverse events and potential aberrant behaviors. The PADT can be used at the initiation of, as well as throughout, treatment with opioid pain medications.

Case: 1:17-md-02804-DAP Doc #: 2295-4 Filed: 08/14/19 7 of 14. PageID #: 362462

Methadone for Chronic Pain Series

Responsible Prescribing of Methadone for Chronic Pain

Item #CA-052

Availability: print, online



Responsible Prescribing of Methadone for Chronic Pain is a reference tool for prescribers considering methadone as a treatment option for their patients with chronic noncancer pain. It consists of 4 chapters covering the risks associated with methadone therapy, the specific and unique pharmacokinetic and pharmacodynamic properties of methadone, appropriate prescribing methods, and additional resources.

Methadone FAQ for Healthcare Professionals

Item #CA-050

Availability: print, online



Methadone FAQ for Healthcare Professionals provides answers to some of the most frequently asked questions that HCPs may have about the characteristics and properties of methadone as well as about ways to responsibly prescribe and ensure the safe use of methadone when used to treat chronic pain. Answers include important information about the unique pharmacokinetic properties of methadone as well as associated risk factors and the safe initiation of methadone therapy.

Methadone Dosing for Chronic Pain

Item #CA-051

Availability: print, online



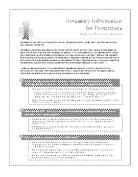
The Methadone Dosing for Chronic Pain brochure is a resource for responsible methadone prescribing and use. The brochure contains valuable information on initiating therapy, dosing and administration, and patient counseling and monitoring that should be reviewed before prescribing methadone.



Methadone Necessary Information for Prescribers

Item #CA-053

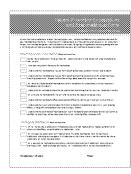
Availability: print, online



The Methadone Necessary Information for Prescribers tool provides background and critical information that HCPs should know before prescribing methadone to treat chronic pain, including instances in which methadone should never be used.

Item #CA-152

Availability: print, online



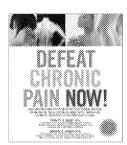
The Methadone Patient-Prescriber
Expectations and Responsibilities Form can be used to set expectations for both the patient and the prescriber at the start of methadone therapy. The HCP can use the points in the form as counseling opportunities. The form also can be used as documentation of patient understanding of the risks associated with methadone treatment, the responsible manner by which the medicine will be received from a pharmacy, and the safe use and handling of methadone.

Patient Tools

Defeat Chronic Pain Now!

Item #CA-102

Availability: print



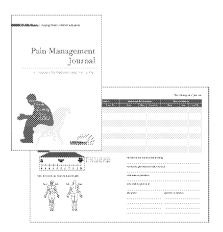
Authored by Bradley S. Galer, MD, and Charles E. Argoff, MD, *Defeat Chronic Pain Now!* provides patients with groundbreaking strategies for eliminating the pain of arthritis, back and neck conditions, migraines, diabetic neuropathy, and chronic illness. The book specifically discusses commonly misdiagnosed pain conditions and cutting-edge treatments currently under development or on the market.

General Opioid Tools

Pain Management Journal

Item #CA-104

Availability: print, online



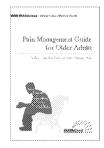
The Pain Management Journal can help the patient track his or her pain and pain management. Filling out the journal will help the patient better communicate with the HCP, which will help both the patient and the HCP get the most out of the patient's pain management program.

Case: 1:17-md-02804-DAP Doc #: 2295-4 Filed: 08/14/19 9 of 14. PageID #: 362464

Pain Management Guide for Older Adults

Item #CA-103

Availability: print, online



The Pain Management Guide for Older Adults can help older patients being treated for chronic pain talk openly with their HCP. This brochure also contains information for the patient on how to safely use and handle opioid prescription pain medicines.



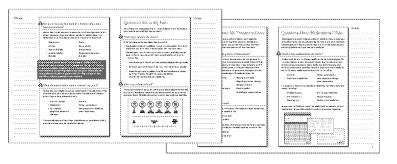
How to Talk to Your Doctor Brochure

Item #CA-105

Availability: print, online



The How to Talk to Your Doctor Brochure encourages open discussion between patients and their HCPs. It describes what patients should tell their doctors, and what their doctors can tell them, so that patients can get the most out of their treatment and keep their families safe.



Opioid Safe Use and Handling Guide

Item #CA-100

Availability: print, online



The Opioid Safe Use and Handling Guide instructs patients on how to safely use and handle opioid medications that have been prescribed to treat their pain. This guide also talks about the risks of treatment with opioids, such as overdose, abuse, and addiction.



American Chronic Pain Association (ACPA) Tools

Availability: online



The ACPA Tools help patients understand what their medicine is, why it was prescribed, and how to safely take it. The tools provide information on what things patients should avoid while taking their medicine and the possible side effects they may experience. They also provide assistance for patients in following up with their doctor, logging their pain, assessing their quality of life, and better describing their pain.

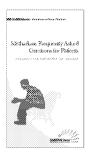
Case: 1:17-md-02804-DAP Doc #: 2295-4 Filed: 08/14/19 10 of 14. PageID #: 362465

Methadone for Chronic Pain Series

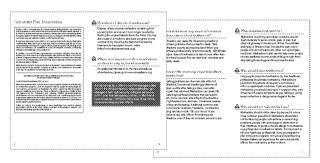
Methadone Frequently Asked Questions for Patients

Item #CA-150

Availability: print, online



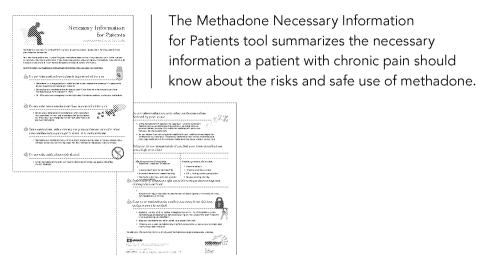
Methadone Frequently Asked Questions for Patients is a resource to help patients safely use methadone when it is prescribed to treat their chronic pain. It answers many questions such as how methadone is different from other pain medicines, who should or should not take methadone, and what to do if a patient accidently takes too much methadone.



Methadone Necessary Information for Patients

Item #CA-151

Availability: print, online



Methadone Safe Use and Handling Guide

Item #CA-153

Availability: print, online



The Methadone Safe Use and Handling Guide is a resource to help patients safely use methadone prescribed to treat their chronic pain. The tool focuses on when and how to take methadone safely to reduce the risk of life-threatening side effects and addiction. It also provides information for the patient on how to store their medicine and how to avoid theft or diversion.



16

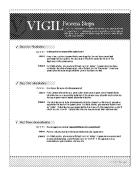
Pharmacist Tools

Verification, Identification, Generalization, Interpretation, and Legalization (VIGIL) Tools

VIGIL Process Steps

Item #CA-201A

Availability: print, online



The VIGIL *Process Steps* details some recommended steps that the pharmacist should take when dispensing opioids to patients in order to mitigate the risk of abuse, misuse, and diversion. Steps include Verification, Identification, Generalization, Interpretation, and Legalization.

VIGIL Medication Use Agreement— High Opioid Volume Pharmacy

Item #CA-201B

Availability: print, online



The VIGIL Medication Use Agreement—High Opioid Volume Pharmacy is a form developed to establish an agreement between the patient being prescribed opioid pain medication and the pharmacist filling the prescription. It documents the patient's understanding of his or her responsibilities when taking the medication and the pharmacist's responsibilities when dispensing it.

VIGIL Pharmaceutical Care Assessment— High Opioid Volume Pharmacy

Item #CA-201C

Availability: print, online



The VIGIL Pharmaceutical Care Assessment— High Opioid Volume Pharmacy is a questionnaire that can help the pharmacist at a high opioid volume pharmacy categorize the level of care required for each patient being prescribed opioid pain medication. This longer questionnaire consists of questions directed to both the patient and the pharmacist.

VIGIL Pharmaceutical Care Assessment Short Form—Low Opioid Volume Pharmacy

Item #CA-201D

Availability: print, online

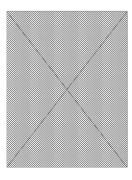


The VIGIL Pharmaceutical Care Assessment Short Form—Low Opioid Volume Pharmacy is a questionnaire that can help the pharmacist categorize the level of care required for each patient being prescribed opioid pain medication. This is a short questionnaire consisting of 12 questions and is meant for use in low opioid volume pharmacies.

VIGIL Pharmaceutical Care Patient Questionnaire

Item #CA-201E

Availability: print, online



The VIGIL Pharmaceutical Care Patient Questionnaire is a short questionnaire consisting of 21 items for the patient to answer to help assess his or her risk of abusing opioid pain medications.

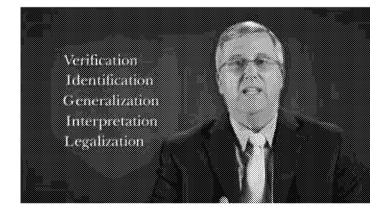
VIGIL Video Series: "Managing the Risks Associated With Dispensing Prescription Opioid Analgesics"

Item #CA-201F

Availability: online, CD-ROM

In this video series, David Brushwood, RPh, JD, Professor of Pharmacy Health Care Administration at the University of Florida, discusses the conflicting therapeutic imperatives faced by pharmacists dispensing opioids to patients with chronic pain in a highly regulated environment. He discusses ethics of pain management, risk factors for misuse, abuse, or diversion of pain medications, and adherence to Drug Enforcement Administration regulations on dispensing of controlled substances. He introduces his key to compliance with responsible opioid dispensing practices—Verification, Identification, Generalization, Interpretation, and Legalization (VIGIL)—and provides background on the VIGIL process and the available VIGIL tools.

- 1. Understanding the Risks
- 2. VIGIL Process Overview
- 3. VIGIL Advanced Tools
- 4. VIGIL Foundational Tools
- 5. VIGIL Case Studies



VIGIL Documentation Stickers

Item #CA-201G

Availability: print, online



The VIGIL Documentation Sticker is a simple tool that documents the 5 VIGIL steps for each patient's prescription—Verification, Identification, Generalization, Interpretation, and Legalization (see VIGIL Process Steps for more information). In addition, it allows for an at-a-glance status of a patient's risk level and care level, as well as the need for counseling or Drug Utilization Review (see VIGIL Pharmaceutical Care Assessment documents).

VIGIL Opioid Talking Points

Item #CA-201H

Availability: print, online



The VIGIL Opioid Talking Points sticker is a 4" x 3.5" sticker that lists the most important safety facts that pharmacists should share with patients before dispensing opioid pain medication. Bulleted points are written in simplified language to help ensure that the patient understands how to take opioid pain medication safely.

VIGIL Memorandum Requesting Pharmacy Consult

Item #CA-201J

Availability: print, online



The VIGIL Memorandum Requesting Pharmacy Consult is a form for use by the pharmacist to request a consultation with the HCP's office regarding a patient's prescription. It can be used by the pharmacist to request verification or clarification of prescription details such as opioid-tolerant status, drug name, or potential modifications to the prescription, or to notify the HCP of issues related to the prescription, such as inadequate insurance coverage or legal issues.

VIGIL Memorandum Confirming Pharmacy Consult

Item #CA-201K

Availability: print, online



The VIGIL Memorandum Confirming Pharmacy Consult is a form for use by the pharmacist and the HCP that verifies and documents new or changed prescriptions for opioid pain medication. The agreement can be used to verify opioid tolerance, prescription modifications, and details on how the prescription was filled, or to clarify questions the pharmacist may have had regarding the prescription.

VIGIL Designating Agent of Practitioner

Item #CA-201M

Availability: print, online



The VIGIL Designating Agent of Practitioner form is intended for use by HCPs registered with the US Drug Enforcement Agency (DEA) to prescribe opioid pain medication under the Controlled Substances Act. With this form, DEA-registered HCPs can authorize another HCP to act as an agent for preparing written prescriptions and communicating these prescriptions to pharmacies. Under the DEA-registered HCP's direction, the authorized agent can prepare written prescriptions, convey oral prescriptions to the pharmacy by telephone, or fax prescriptions to the pharmacy, when appropriate.

General Tools

Pharmacist's Manual

Item #CA-200

Availability: print, online



The *Pharmacist's Manual* is prepared by the Drug Enforcement Agency, Office of Diversion Control, as a guide to assist pharmacists in their understanding of the Federal Controlled Substances Act and implementing its regulations as they pertain to the pharmacy profession.

Order Form

Please fill out the contact information below and check the boxes for the desired C.A.R.E.S. Alliance tools before placing this order form in the mail. For videos and other items available	Patient Tools
online only, visit the C.A.R.E.S. Alliance Web site at www.caresalliance.org.	☐ Defeat Chronic Pain Now! (CA-102)
Name:Date:	General Opioid Tools
Organization:	Pain Management Journal (CA-104)
Street Address:	Pain Management Guide for Older Adults (CA-103)
	☐ How to Talk to Your Doctor Brochure (CA-105)
City: State: Zip Code:	☐ Opioid Safe Use and Handling Guide (CA-100)
Providence/Territory: International Postal Code: Country:	Methadone for Chronic Pain Series
Phone: Fax: E-mail Address:	☐ Methadone Frequently Asked Questions for Patients (CA-150)
	☐ Methadone Necessary Information for Patients (CA-151)
Prescriber Tools	☐ Methadone Safe Use and Handling Guide (CA-153)
General Opioid Management Tools Opioid Clinical Management Guide (CA-012)	Pharmacist Tools
Opioid Clinical Management Checklist (CA-013)	Verification, Identification, Generalization, Interpretation, and
Opioid Treatment Guidelines Reprint Carrier (CA-003RC)	Legalization (VIGIL) Tools
☐ Universal Precautions in Pain Medicine Reprint Carrier (CA-006B)	
☐ Urine Drug Screening (UDS) Reprint Carrier (CA-005RC)	 □ VIGIL Process Steps (CA-201A) □ VIGIL Medication Use Agreement—High Opioid Volume Pharmacy (CA-201B)
☐ Urine Drug Testing (UDT) Brochure (CA-016)	□ VIGIL Pharmaceutical Care Assessment—High Opioid Volume Pharmacy (CA-2010)
□ Patient-Prescriber Expectations and Responsibilities Form (CA-010)	□ VIGIL Pharmaceutical Care Assessment Short Form—Low Opioid Volume Pharmacy (CA-201D)
Responsible Opioid Prescribing: A Physician's Guide (CA-002)	
☐ Opioid Prescribing Toolkit (CA-004)	☐ VIGIL Pharmaceutical Care Patient Questionnaire (CA-201E)
Validated Tools	 VIGIL Video Series: "Managing the Risks Associated With Dispensing Prescription Opioid Analgesics" (CA-201F)
☐ Brief Pain Inventory (BPI) (CA-007A)	□ VIGIL Documentation Stickers (CA-201G)
□ Numeric Rating Scale (NRS) and Wong-Baker Faces Pain Rating Scale (CA-007B)	☐ VIGIL Opioid Talking Points (CA-201H)
☐ Opioid Risk Tool (ORT) (CA-007C)	☐ VIGIL Memorandum Requesting Pharmacy Consult (CA-201J)
□ Pain Assessment and Documentation Tool (PADT™) (CA-007D)	□ VIGIL Memorandum Confirming Pharmacy Consult (CA-201K)
Methadone for Chronic Pain Series	□ VIGIL Designating Agent of Practitioner (CA-201M)
Responsible Prescribing of Methadone for Chronic Pain (CA-052)	General Tools
☐ Methadone FAQ for Healthcare Professionals (CA-050)	☐ Pharmacist's Manual (CA-200)
☐ Methadone Dosing for Chronic Pain (CA-051)	· ,
☐ Methadone Necessary Information for Prescribers (CA-053)	
☐ Methadone Patient-Prescriber Expectations and Responsibilities Form (CA-152)	

